DENTIFRICE COMPOSITIONS CONTAINING β-PHASE CALCIUM PYROPHOSPHATE AN ANTICALCULUS AGENT, AND FLUORIDE

BACKGROUND OF THE INVENTION

Dental calculus, or tartar as it is sometimes called, is a deposit which forms on the surfaces of the teeth at the gingival margin. Supragingival calculus appears principally in the areas near the orifices of the salivary ducts; e.g., on the lingual surfaces of the lower anterior teeth and on the buccal surfaces of the upper first and second molars, and on the distal surfaces of the posterior molars.

Mature calculus consists of an inorganic portion which is largely calcium phosphate arranged in a hydroxyapatite crystal lattice structure similar to bone, enamel, and dentine. An organic portion is also present and consists of desquamated epithelial cells, leukocytes, salivary sediment, food debris, and various types of microorganisms.

As the mature calculus develops, it becomes visibly white or yellowish in color unless stained or discolored by some extraneous agent. This is undesirable from an aesthetic standpoint. Mechanical removal of calculus periodically by the dentist is routine dental office procedure. A variety of chemical and biological agents have also been suggested to retard calculus formation or to remove calculus after it is formed. Pyrophosphate salts are chemical agents known to have the ability to retard calculus formation as described, for example, in U.S. Pat. No. 4,999,184, issued Mar. 12, 1991, and U.S. Pat. No. 4,590,066, issued May 20, 1986, both to Parran, Jr. et al., the disclosures of which are incorporated herein by reference in their entirety.

In addition to the pyrophosphate salts, polyphosphates are also know to help retard calculus formation. U.S. Pat. No. 4,627,977, issued Dec. 9, 1986, to Gaffar et al. discloses the use of linear molecularly dehydrated polyphosphate salt in combination with two additional ingredients which inhibit enzymatic hydrolysis of the polyphosphate. U.S. Pat. No. 4,247,526, to Jarvis et al., issued Jan. 27, 1981, discloses the use of a pharmaceutically acceptable condensed phosphate salt in addition to trimagnesium phosphate and dicalcium phosphate dihydrate, a calcium containing abrasive. This patent also discloses a method of stabilizing the dicalcium phosphate dihydrate.

As in Jarvis et al., calcium containing abrasives have been used in toothpaste compositions. However, the calcium ions in these materials will complex with free fluoride ions causing a potential decrease in caries efficacy. Therefore, calcium containing abrasives, such as calcium pyrophosphate, are not preferred abrasives in dentifrice compositions comprising free fluoride ions. Calcium containing abrasive compositions comprising a covalently bonded fluoride source, such as monofluorophosphate, are more stable than compositions comprising an ionic fluoride source.

To help stabilize calcium pyrophosphate, β-phase calcium pyrophosphate is formed by the process described by Schweizer, U.S. Pat. No. 3,112,247, issued Nov. 26, 1963. Although fluoride ions are more stable when combined with the β-phase calcium pyrophosphate than untreated calcium pyrophosphate, the β-phase calcium pyrophosphate is still not preferred, as the fluoride stability can still be significantly improved. For example, see U.S. Pat. No. 5,338,537, to White, Jr. et al., issued Aug. 16, 1994. Typical ionic fluoride stability with β-phase calcium pyrophosphate is approximately 50–60% after several months. Although

β-phase calcium pyrophosphate is difficult to stabilize with respect to ionic fluoride, β-phase calcium pyrophosphate remains a preferred abrasive because of its superior cleaning properties versus the more commonly used abrasive, such as silica.

Therefore, there is a need to develop stable dentifrice formulas comprising ionic fluoride and β-phase calcium pyrophosphate. The present inventors have discovered that by adding a selected anticalculus agent to β-phase calcium pyrophosphate, the β-phase calcium pyrophosphate can be greatly inhibited from complexing with fluoride. In addition to the maintenance of fluoride stability and therefore, anticaries efficacy, the antitartar activity is also maintained. Therefore, the dentifrice composition comprising a specific amount of β-phase calcium pyrophosphate provides excellent cleaning and anticaries and anticalculus efficacy.

It is an object of the present invention to provide dentifrice compositions providing maximum fluoride stability and excellent cleaning. It is an object of the present invention to provide a dentifrice composition comprising β-phase calcium pyrophosphate, an anticalculus agent, and fluoride ion source. The anticalculus agent may be a diphosphonate source, a polyphosphate source, a pyrophosphate source, or combination thereof.

These and other objects of the present invention will become readily apparent from the detailed description which follows.

All percentages and ratios used herein are by weight of the dentifrice composition, unless otherwise specified. All measurements are made at 25° C., unless otherwise specified.

SUMMARY OF THE INVENTION

The present invention relates to dentifrice compositions comprising from about 30% to about 45% of β-phase calcium pyrophosphate, an anticalculus agent, a soluble fluoride ion source capable of providing from about 50 ppm to about 3500 ppm of free fluoride ions, and one or more aqueous carriers. The anticalculus agent may be a polyphosphonate source, a polyphosphate source, or a pyrophosphate source.

DETAILED DESCRIPTION OF THE INVENTION

The term "dentifrice composition" as used herein means paste, gel, or liquid formulations unless otherwise specified. The dentifrice composition may be in any desired form, such as deep striped, surface striped, multilayered, having the gel surrounding the paste, or any combination thereof. The dentifrice composition is a product, which in the ordinary course of usage, is not intentionally swallowed for purposes of systemic administration of particular therapeutic agents, but is rather retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces and/or oral tissues for purposes of oral activity.

The term "dispenser", as used herein, means any pump, tube, or container suitable for dispensing toothpaste.

The term "aqueous carrier" as used herein means any safe and effective materials for use in the compositions of the present invention. Such materials include additional abrasive polishing materials, peroxide sources, alkali metal bicarbonate salts, thickening materials, humectants, water, surfactants, titanium dioxide, buffering agents, antimicrobial agents, flavor system, sweetening agents, xylitol, coloring agents, and mixtures thereof.

The present compositions comprise essential components, as well as optional components. The essential and optional